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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EVANS, ERIN LINDSAY	

ART UNIT	PAPER NUMBER
4172	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,192	SIEBEN ET AL.	
	Examiner	Art Unit	
	ERIN EVANS	4172	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/16/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/15/2007, 02/22/2005, 10/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction Requirement Withdrawn

1. Restriction was previously required under 35 U.S.C. 121 and 372 between the inventions contained in groups I and II, however this restriction is withdrawn based on the preliminary amendment filed on 04/16/2008.

This application previously contained the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claim(s) 1-7, drawn to a method of immobilizing molecules on a surface on which electrical sensors and process circuits are integrated by applying a layer of hydrophobic polymer and immobilizing molecules on the surface of the layer.

Group II, claim(s) 8-21, drawn to method of immobilizing molecules on a surface by applying a layer of hydrophobic polymer and immobilizing molecules on the surface of the layer.

2. During a telephone conversation with Patrick O'Shea on the 17th of April, 2008 a provisional election was made with traverse to prosecute the invention of II, claims 8-21. However, based on the preliminary amendment wherein claim 1 was canceled and claims 2-7 were made to depend from claim 8, there are no longer two separate inventions, and the restriction requirement is withdrawn.

Status of Application

3. Claims 2-21 are pending in the application.

4. Claim 1 has been canceled.

5. Claims 2-21 are presented for examination. The following rejections are made.

Specification

6. The disclosure is objected to because of the following informalities: improper layout.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Objections

Duplicate Claims

Comment [v1]: Please change to "Duplicate claims"

7. Applicant is advised that should claim 5 be found allowable, claim 13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2-4, 6, 8-12, and 14-17 rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,700,559 (henceforth '559).

Claims 2-4, 6, 9-12, and 14-17 depend from independent claim 8, which is drawn to a method of immobilizing molecules on a surface using the steps of applying a layer

of hydrophobic polymer to the surface and then immobilizing molecules onto the surface of the polymer layer.

'559 discloses durable hydrophilic surface coatings in which a substrate is coated with an ionic polymer layer onto which a polyelectrolyte coating is bound (Abstract). The polymeric coating can be hydrophobic (Column 1 lines 35-37). Claim 8 is thus fully anticipated by '559.

Further, the polymer may be polyimide (Column 6 line 4) or polystyrene (Column 2 line 24). Claims 2, 9, and 10 are thus anticipated by the teachings of '559.

It is further disclosed that the polymeric layer may be applied to selected areas on the substrate, and thus at least one defined region must be defined on the surface, followed by applying the layer of hydrophobic polymer to the at least one defined region on the surface, for instance a pair of polymeric strips across the substrate (Column 3 lines 35-40). Claims 3 and 11 are therefore anticipated by '559.

In order to obtain the ionic polymer layer, '559 teaches that a plasma discharge treatment may be used (Column 6 lines 28-30). In the case for obtaining an anionic polymer, the plasma treatment may use oxidizing gases such as oxygen (Column 6 lines 42-43). An electric charge is therefore imparted on the layer, and the layer is activated, by this treatment. This treatment is applied to the entire surface of the polymer layer, and would therefore be applied at least in sectional fashion. Thus, claims 4, 6, 12, and 14 are fully anticipated by '559.

'559 further teaches that the polyelectrolyte coating that is immobilized on the polymer layer can be intermixed with non-polyelectrolyte additives, such as the

bioactive molecule heparin, a biological molecule (Column 1 lines 63-65). Therefore, claim 15 is anticipated by the teachings of '559.

The examples given for species of polymer layers in '559 includes polyethylene, a non-swelling polymer, anticipating current claim 16 (Column 2 line 24).

Materials listed as possible substrate materials include metal, ceramic, and glass, each of which are inorganic materials (Column 4 lines 25-28). Claim 17 is therefore anticipated by '559.

Claims 2-4, 6, 8-12, and 14-17 are thus rejected under 35 U.S.C. 102(b) as being unpatentable over US Patent No. 5,700,559.

10. Claims 2, 5, 8-10, 13, 15, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,465,151 (henceforth '151).

These claims are drawn to a process of immobilizing molecules on a surface wherein a hydrophobic polymer layer is first applied to the surface followed by the immobilization of the molecules to the surface of the polymer layer. These claims are further drawn to the process wherein UV-reactive molecules are immobilized covalently using UV-irradiation, and wherein the surface is an inorganic semiconductive material.

'151 teaches the production of chemical sensors and biosensors using functionalized waveguides (Abstract). The waveguide can be made of rigid base materials including (inorganic) semiconducting silicon-dioxide (Column 9 lines 6-10), onto which polymer waveguide materials are coated. Suitable waveguide materials are listed in Table 1 and include polystyrene, but it is mentioned that polyimides are also

suitable candidates (Column 10 lines 46-47). The surface is then functionalized by the covalent immobilization of molecules (Abstract). Therefore Claim 8, and dependent claims 2, 9-10, and 17-20 are fully anticipated by '151.

'151 further teaches the functionalization of the polymer waveguide materials using a "reaction-energy source" such as UV (Column 13 lines 19-25) to covalently link molecules to the surface (Column 13 lines 40-43). Here, the waveguide surface is understood to be the surface of the polymer material used on top of the rigid base semiconductor material. These covalently linked molecules can then participate in binding of other functional groups, including biological molecules (Abstract). Hence, current claims 5, 13, and 15 are also anticipated by '151.

Claims 2, 5, 8-10, 13, 15, and 17-20 are thus rejected under 35 U.S.C. 102(b) as being unpatentable over US Patent No. 5,465,151.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 7, 8, 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,560,471 (henceforth '471) in view of US-20030108879 (henceforth '879).

Claims 7, 8, 15 and 21 are drawn to the method of immobilizing molecules on surfaces as described in paragraph 9 above. However, these claims provide further limitations wherein the surface of the polymer layer is utilized for application with an integrated circuit and the surface to be coated includes a surface of a support in which electrical sensors and processor circuits are integrated.

'471 teaches the fabrication of an analyte sensor (Abstract). The sensor 42 comprises a substrate 50 which has a sensing layer 64 (Figure 2) disposed thereon. The sensing layer contains immobilized compounds such as catalysts (Column 16 lines 12-18), which are immobilized, for example, by entrapping within a polymeric matrix (Column 16 lines 25-29). The polymer layer itself is disposed on the electrode on the substrate (Column 8 lines 1-6). Therefore the sensing layer is formed directly on an electrode at the tip of the sensor (Column 16 lines 6-8) and electric sensors are integrated in the surface onto which the molecules are immobilized (Current claims 8 and 21).

The sensor is also integrated with the sensor control unit in Figures 18A and 18B, which includes processing circuits (109 in Figures 18A and 18B). Further, the substrate and immobilized sensing layer are a part of an integrated circuit in the

embodiment of Fig 32 (Column 33 lines 10-21). In one example, the compound which is immobilized within the sensing layer is an enzyme (Column 17 lines 24-27), and '471 thus teaches the immobilization of biomolecules.

'471 does not teach that the polymeric matrix of the sensing layer is a hydrophobic polymer layer.

'879 teaches sensors which use polymeric brushes to immobilize molecules to a surface or substrate. The polymer layer includes a first hydrophobic polymer segment bound to the substrate (Abstract). The sensors have improved stability in aqueous environments because the layer of hydrophobic polymer renders a more stable bond, and thus have the benefits of being reusable and the capability of use in more extreme conditions [0028].

It was therefore known to those of ordinary skill in the art at the time of the present invention that use of a hydrophobic polymer layer has the stated benefits of increased stability. One would have been motivated to combine the teachings of '471 with those of '879 to arrive at the present invention because the sensor of '471 would need to be more stable in aqueous environments, since it is being implanted in human patients.

Claims 2, 8, 15 and 21 are therefore made obvious by '471 in view of '879, and are rejected under 35 U.S.C. 103(a).

Conclusion

14. Claims 2-21 are pending in the application.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN EVANS whose telephone number is (571)270-5354. The examiner can normally be reached on Monday through Friday from 7:30am to 5pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIN EVANS/
22 April 2008
Examiner, Art Unit 4172

/Vickie Kim/
Supervisory Patent Examiner, Art Unit 4172